

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, October 31, 2016 8:55 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Atrium Trocar Catheter products

This notification is to inform you of an urgent medical device recall involving the removal of all lot numbers of Atrium Trocar Catheter products. The Atrium Trocar Catheters are sterile, single use, disposable devices, and are intended to facilitate the evacuation of air and/or fluid from the chest cavity or mediastinum. The product code numbers affected by this recall are listed in the table below. All lot numbers are affected. All sterile and un-used affected products should be returned to Atrium for credit. Replacement product is not available as all Trocar Catheters have been discontinued. Atrium Trocar Catheters are packaged with a label containing an icon that shows more holes (eyelets) than the product actually contains. Although the use of a trocar catheter with two eyelets may be effective in most patients, the potential risks related to use of the trocar catheter with 2 eyelets are: incomplete drainage of pleural effusion or pneumothorax, the need for repeat chest tube or pleural drain insertion, and surgical site infection.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

Code Number	Product Description
8408	8 Fr Trocar catheter
8410	10 Fr Trocar catheter
8412	12 Fr Trocar catheter
8416	16 Fr Trocar catheter
8420	20 Fr Trocar catheter
8424	24.Fr Trocar catheter
8428	28 Fr Trocar catheter
8432	32 Fr Trocar catheter